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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,159	01/20/2004	William J. Boyle	A-378CIP2C5	3751

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AMGEN INC.
US Patent Operations/RBW
Dept. 4300, M/S 27-4-A
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,159	BOYLE ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49,51-53 and 61-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49,51-53 and 61-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendments filed 20 January 2004 and 15 September 2004 have been entered in full. Claims 1-48, 50, 54-60 are cancelled. New claims 61-76 are added.

Claims 49, 51-53, 61-76 are under examination.

Information Disclosure Statement

The information disclosure statement(s)(IDS) filed 30 July 2004 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Sequence Rules

The specification is not in compliance with 37 CFR 1.821-1.825 of the Sequence Rules and Regulations. When the description of a patent application discusses a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of the Sequence Rules and Regulations, reference must be made to the sequence by use of the assigned identifier (SEQ ID NO:), in the text and claims of the patent application. 37 CFR 1.821(a) presents a definition for nucleotide and/or amino acid sequences. This definition sets forth limits in terms of numbers of amino acids and/or numbers of nucleotides, at or above which compliance with the sequence rules is required. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or

an unbranched sequence of ten or more nucleotides. Please see MPEP section 2422.01.

The specification refers to sequences in Figures 1A-B, 2B-C, 9A-F, 10 and 12A-B (bottom sequence) and on page 85, line 31 and page 96, lines 30-31, but does not identify the sequences by their sequence identifiers. Sequences appearing in drawings should be referenced in the corresponding Brief Description thereof. See 37 C.F.R. §1.58(a) and §1.83. Appropriate correction is required.

Appropriate correction is required. Applicant must submit a response to this Office Action and compliance with the sequence rules within the statutory period set for response to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49, 51-53, 61-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for **treating** a bone disorder associated with loss of bone density,

does not reasonably provide enablement for:

a method for **preventing** a bone disorder associated with loss of bone density. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate

in scope with these claims. The word "prevents" means to stop or inhibit the onset (of a bone disorder). "Prevention" is not a relative term, it is total. The state of the prior art establishes various treatments for the diseases claimed in the instant application. A very high degree of evidence is required, which is accepted in the art, that an absolute protection from the pathology exists over an extended period of time. The specification fails to teach how to prevent a bone disorder associated with the loss of bone density.

Due to the large quantity of experimentation necessary to show that the onset of the claimed disease or condition has been prevented, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples, the complex nature of the invention, and the breadth of the claims which fail to recite any parameters set for the prevention of bone disorders associated with loss of bone density, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 49-64, 67, 69-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

"a method...wherein the OPG polypeptide comprises a carboxy-terminal truncation of part or all of the amino acid residues 185-401 from residues 22 to 401 shown in SEQ ID NO:125",

does not reasonably provide enablement for:

"a method....an OPG polypeptide comprises a truncation of the amino acid sequence from residues 22 to 401 shown in SEQ ID NO:125" (claim 49).

OR

"a method...wherein the OPG polypeptide comprises a carboxy-terminal truncation of the amino acid sequence from residues 22 to 401 shown in SEQ ID NO:125" (claim 62).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification teaches that amino acid residues 22-185 define a region for OPG activity (page 124, lines 20-24). The instant specification does not teach how to use an inactive OPG polypeptide for treating bone disorders associated with loss of bone density.

Due to the large quantity of experimentation necessary to use an inactive OPG polypeptide, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples, the complex nature of the invention, and the breadth of the claims which fail to recite any parameters for using inactive OPG polypeptides for the prevention of bone disorders associated with loss of bone density, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49-53, 61-63, 65, 67-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-14 of U.S. Patent No. 6,288,032 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are generally drawn to a method of preventing or treating a bone disorder comprising administering therapeutically amounts of OPG polypeptide (SEQ ID NO:125). The claims are also drawn to administering therapeutically effective amounts of various proteins.

Claims 10-14 in Patent No. '032 B1 are drawn to pharmaceutical compositions comprising SEQ ID NO:6 and methods of treating a bone disorder comprising administering pharmaceutical compositions comprising SEQ ID NO:6 and effective amounts of other proteins. SEQ ID NO:6 is human osteoprotegerin (OPG). SEQ ID NO:6 in Patent No. '032 B1 comprises amino acid residues that overlap amino acid residues comprising human OPG (SEQ ID NO:125) in the instant claims. The species of human OPG recited in the patented claims renders obvious its variants recited in the pending claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
11/18/05

JOSEPH MURPHY
PATENT EXAMINER